

What is Claimed is:

1. A balloon catheter stent deployment system comprising:
 - a balloon catheter comprising:
 - an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and
 - an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof,
 - 10 an expandable tubular stent mounted around the balloon, the stent having a distal end disposed proximally to the distal end of the balloon and a proximal end spaced distally from the proximal end of the balloon, the stent being crimped onto the balloon so the stent has an initial maximum outer diameter when the balloon is in an uninflated state,
 - 15 the balloon further comprising a proximal section extending beyond the proximal end of the stent to a point where the balloon is attached to the outer shaft, the proximal section of the balloon having an uninflated initial outer diameter greater than the initial outer diameter of the stent, and
 - the balloon further comprises a distal section extending beyond the distal end of the stent to a point where the balloon is attached to the inner shaft, the distal section of the balloon having an uninflated initial maximum outer diameter less than or equal to the initial maximum outer diameter of the stent.
2. The system of claim 1 wherein the proximal section of the balloon has a diameter greater than the distal section of the balloon.
3. The system of claim 1 wherein the inner tube extends beyond a point where the distal end of the balloon is attached thereto by a distance ranging from about 2 to about 5 mm.
- 30 4. The system of claim 1 wherein the balloon comprises a material selected from the group consisting of nylon, PET, PEEK, PEBAK and mixtures thereof, co-extrusions thereof or laminations thereof.

5. The system of claim 1 wherein balloon comprises a plurality of folds disposed beneath the stent and the proximal section of the balloon being substantially devoid of folds.

5. 6. The system of claim 1 wherein the stent is a cylindrical wire mesh.

7. The system of claim 1 wherein the stent is fabricated from a material selected from the group consisting of stainless steel, NITNOL, niobium, 10 cobalt and alloys thereof.

8. The system of claim 1 wherein the proximal section of the balloon has a uniform maximum initial outer diameter for providing a centering action when the system is moved longitudinally in a vascular system.

15. 9. A method for fabricating a balloon catheter stent deployment system, the method comprising:

providing a balloon catheter comprising

an inner tubular shaft disposed within an outer tubular shaft, the 20 inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and

an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof;

25 placing a stent over the balloon so that a distal end of the stent is disposed proximally to the distal end of the balloon and a proximal end of the stent is spaced distally from the proximal end of the balloon leaving a proximal section of the balloon uncovered by the stent that extends from the proximal end of the stent to the proximal end of the balloon,

30 crimping the stent onto the balloon to leave the stent with initial outer diameter,

placing a stepped enclosure over the stent and balloon wherein the stepped enclosure comprising a first section having a first inner diameter and that is connected to a second section having a second inner diameter, the first inner diameter being greater than or equal to the second inner diameter, the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto, the second section of the stepped enclosure being at least as long as the stent, and wherein the first section of the stepped enclosure is disposed over the proximal section of the balloon and the second section of the stepped enclosure is disposed over the stent,

10 inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent and balloon disposed beneath the stent and distally of the stent are prevented from substantial expansion by the second section of the stepped enclosure,

removing the balloon and stent from the stepped enclosure.

15 10. The method of claim 9 further comprising:
 inserting a protective sleeve over the stent after removing the balloon and stent from the stepped enclosure.

20 11. The method of claim 9 further comprising:
 inserting a protective sleeve over the balloon catheter to a position proximal to the stent and balloon before placing the stent over the balloon, and
 sliding the protective sleeve over the stent after removing the stepped tube.

25 12. The method of claim 9 wherein the first section of the stepped tube comprises a flared proximal distal end and the second section of the stepped tube comprises a flared proximal end.

30 13. The method of claim 9 wherein the stepped enclosure is a stepped tube and the second section of the stepped tube extends into the first section of the stepped tube to provide an overlap section between the first and second sections.

14. The method of claim 9 wherein the stepped enclosure is formed by a plurality of crimping elements each having a stepped leading edge to form the stepped enclosure and wherein the plurality of crimping elements are movable between crimping and retracted positions.

5

15. The method of claim 14 wherein the plurality of crimping elements comprise part of a crimping device capable of heating the stent and balloon during the crimping of the stent onto the balloon.

10

16. The method of claim 9 wherein the crimping further comprises heating the stent and balloon to a temperature ranging from about 50 to about 85°C.

15

17. The method of claim 9 wherein the crimping further comprises heating the stent and balloon to a temperature of about 65°C.

15

18. The method of claim 9 wherein the inflating further comprises inflating the balloon with a gas having a temperature ranging from about 40 to about 60°C.

20

19. The method of claim 9 wherein the inflating further comprises pressurizing the balloon to an internal pressure ranging from about 30 to about 75 psi for a time period ranging from about 5 seconds to about 1 minute.

25

20. The method of claim 9 wherein the inflating further comprises inflating the balloon with a gas having a temperature ranging from about 40 to about 60°C and pressurizing the balloon to an internal pressure ranging from about 30 to about 75 psi for a time period ranging from about 5 seconds to about 1 minute.

21. A tool for fabricating a self-centering balloon catheter stent deployment system, the tool comprising:

a stepped tube comprising a first section having a first inner diameter and that is connected to a second section having a second inner diameter, the first inner diameter being greater than the second inner diameter,

the second inner diameter being greater than an initial outer diameter of a stent as crimped onto a balloon but in close approximation thereto to prevent substantial expansion of the stent and a portion of the balloon disposed beneath the stent upon pressurization of the balloon, the second section of the stepped tube being longer than the stent,

the first inner diameter of the first section being larger than an initial diameter of a portion of the balloon not covered by the stent to permit expansion of the balloon upon pressurization thereof.

15 22. The method of claim 21 wherein the first section of the stepped tube comprises a proximal distal end and the second section of the stepped tube comprises a flared proximal end.

20 23. The method of claim 21 wherein the second section of the stepped tube extends into the first section of the stepped tube to provide an overlap section between the first and second sections.

24. The device for fabricating a self-centering balloon catheter stent deployment system, the device comprising:

25 a plurality of crimping elements, each crimping element having a leading edge, each leading edge having a cut-out portion, the leading edges and cut-out portion of each crimping element being movable from a retracted position to a crimping position, the cut-out portions of each leading edge defining a first section having a first inner diameter and the portions of the leading edges not disposed within the cut-out portions defining a second section having a second inner diameter when the crimping elements are in the crimping position, the first inner diameter being greater than the second inner diameter,

the second inner diameter being greater than or equal to an initial outer diameter of the stent as crimped onto a balloon,

the first inner diameter being larger than an initial diameter of a proximal portion of the balloon not covered by the stent to permit expansion of the balloon upon pressurization thereof.

5 25. The device for fabricating a self-centering balloon catheter stent deployment system, the device comprising:

a plurality of crimping element pairs, each pair comprising a first crimping element and a second crimping element, each crimping element having a leading edge, the leading edge of each crimping element being movable from a retracted position to a crimping position, the leading edge of each first crimping element defining a first section having a first inner diameter and the leading edges of the second crimping elements defining a second section having a second inner diameter when the crimping elements are in the crimping position, the first inner diameter being greater than the second inner diameter,

15 the second inner diameter being greater than or equal to an initial outer diameter of the stent as crimped onto a balloon,

the first inner diameter being larger than an initial diameter of a proximal portion of the balloon not covered by the stent to permit expansion of the balloon upon pressurization thereof.

20 26. A balloon catheter stent deployment system comprising:
a balloon catheter comprising
an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and

25 an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof,

30 an expandable tubular stent mounted around the balloon, the stent having a distal end disposed near the distal end of the balloon and a proximal end spaced distally from the proximal end of the balloon, the stent being crimped onto the balloon so the stent had an initial maximum outer diameter when the balloon is in an uninflated state,

the balloon further comprising a proximal section extending from the proximal end of the stent to a point where the balloon is attached to the outer shaft, the proximal section of the balloon having a uniform uninflated initial maximum outer diameter greater than the initial outer diameter of the stent to thereby provide a

5 centering action when the system is moved longitudinally in a vascular system, and

the balloon further comprising a distal section extending from the distal end of the stent to a point where the balloon is attached to the inner shaft, the distal section of the balloon having an uninflated initial maximum outer diameter less than or equal to than the initial maximum outer diameter of the stent.

10

27. A balloon for intravenous use, the balloon comprising:
a proximal end and a distal end, the balloon being wrapped into a cylindrical configuration, a total length of the balloon extending from the proximal to distal ends comprising a proximal section, a middle section and a distal section,

15

the proximal section extending from the proximal end to the middle section, the middle section extending from the proximal section to the distal section, the distal section extending from the middle section to the distal end,

20

the proximal section having an initial diameter that is greater than initial diameters of the middle and distal sections, the middle section having a length that is greater than either the proximal or distal sections.

25
28. The balloon of claim 27 wherein the proximal distal end is connected to a first tubular shaft and the distal end is connected to a second tubular shaft, the second tubular shaft extends through and beyond the first tubular shaft.

29. The balloon of claim 27 wherein a cylindrical stent is crimped onto the middle section of the balloon.

30

30. The balloon of claim 27 wherein, upon inflation, the diameters of the proximal, middle and distal end are approximately equal.